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FISCAL IMPACT STATEMENT

LS 6891

BILL NUMBER: SB 321

NOTE PREPARED: Jan 20, 2005

BILL AMENDED:

SUBJECT: Wholesale Drug Distributor Licensure.

FIRST AUTHOR: Sen. Riegsecker

BILL STATUS: As Introduced

FIRST SPONSOR:

**FUNDS AFFECTED: X GENERAL
DEDICATED
FEDERAL**

IMPACT: State

Summary of Legislation: This bill expands the requirements that must be met by a wholesale drug distributor for eligibility for licensure. The bill specifies prohibited acts. It also specifies criminal acts related to wholesale drug distribution and legend drugs and devices.

Effective Date: July 1, 2005.

Explanation of State Expenditures: *Summary:* This bill expands the requirements that a wholesale drug distributor must meet in order to be eligible for licensure in Indiana. The Board of Pharmacy already licenses approximately 820 wholesale drug distributors, of which 576 are located out of state. The bill will require national accreditation of wholesale drug distributors. The bill also allows the Board to promulgate rules to accept the accrediting body's conduct of on-site surveys that will meet Indiana licensure requirements. Indiana inspectors will also continue to inspect wholesale distributors located in the state. Currently, the National Association of Boards of Pharmacy (NABPR) has an accreditation process and has recently implemented an inspection service. The cost of the accreditation and inspections is borne by the applicant seeking accreditation and licensure. The Board of Pharmacy has reported that the promulgation of new rules associated with the bill can be accomplished within the level of resources currently available to the Board.

National Criminal History Background Checks: The bill requires the Board to consider the results of national criminal history background checks. Currently, the Board does not require any criminal history checks for wholesale drug distributor licensure. The Indiana State Police charge \$39 for the searches of the FBI national data base; \$24 of the fee goes to the FBI for the data base search, and \$15 is retained by the State Police for deposit in the state General Fund. Fingerprinting is a required component of the national criminal history background check. If the fingerprinting is performed by the State Police, there is no additional charge. If

fingerprinting is performed by a local agency, a fingerprinting fee may be assessed depending upon local policy. The bill requires the applicant for the wholesale drug distributor license to bear the expense of the criminal history background checks.

Pedigree Requirements: The bill requires that wholesale drug distributors keep and routinely authenticate legend drug or device pedigrees. The pedigree is a document that may be kept in written or electronic form that records each distribution of a legend drug or device from the original sale by the manufacturer through the acquisition and sale by each wholesale drug distributor. The pedigree must include specific information outlined in the bill. Pedigrees will be required to be maintained in a written or electronic format after December 31, 2006. This provision is a record keeping requirement of the wholesale drug distributors and will have a fiscal impact on the Board only to the extent that it affects the rules to be promulgated to implement this bill.

Penalty Provisions: The bill creates two new criminal penalties: (1) legend drug or device deception resulting in death, a Class A felony; and (2) legend drug or device deception, a Class D felony. The bill also expands the existing Class D felony for engaging in wholesale drug distribution without a license, to include fraudulent actions concerning record keeping requirements associated with the wholesale distribution of legend drugs or devices.

A Class A felony is punishable by a prison term ranging from 20 to 50 years depending upon mitigating and aggravating circumstances. A Class D felony is punishable by a prison term ranging from six months to three years or reduction to Class A misdemeanor depending upon mitigating and aggravating circumstances.

The average expenditure to house an adult offender was \$21,514 in FY 2004, ranging from a low of \$16,645 to a high of \$49,281. (This does not include the cost of new construction.) If offenders can be housed in existing facilities with no additional staff, the average cost for medical care, food, and clothing is approximately \$1,825 annually, or \$5 daily, per prisoner. The average length of stay in Department of Correction (DOC) facilities for all Class D felony offenders is approximately ten months. The average length of stay for all Class A felony offenders is approximately 9.1 years.

Explanation of State Revenues: *Fees:* Currently, the state license fee for wholesale drug distributors, regardless of location, is \$100 every 2 years. The level of fees that may be charged to cover expenses of the Board of Pharmacy would be dependent upon actions of the Board and the number of distributors continuing licensure. There are currently about 820 licensed distributors. Of these, 244 are located in state, while 576 are located out of state.

Penalty Provisions: If additional court cases occur and fines are collected, revenue to both the Common School Fund and the state General Fund would increase. The maximum fine for a Class D felony and a Class A felony is \$10,000. Criminal fines are deposited in the Common School Fund.

If the case is filed in a circuit, superior, or county court, 70% of the \$120 court fee that is assessed and collected when a guilty verdict is entered would be deposited in the state General Fund. If the case is filed in a city or town court, 55% of the fee would be deposited in the state General Fund.

Explanation of Local Expenditures: *Penalty Provisions:* If more defendants are detained in county jails prior to their court hearings, local expenditures for jail operations may increase. The average cost per day is approximately \$44.

Explanation of Local Revenues: *Penalty Provisions:* If additional court actions occur and a guilty verdict is entered, local governments would receive revenue from the following sources: (1) The county general fund would receive 27% of the \$120 court fee that is assessed in a court of record. Cities and towns maintaining a law enforcement agency that prosecutes at least 50% of its ordinance violations in a court of record may receive 3% of court fees. (2) A \$3 fee would be assessed and, if collected, would be deposited into the county law enforcement continuing education fund. (3) A \$2 jury fee is assessed and, if collected, would be deposited into the county user fee fund to supplement the compensation of jury members.

State Agencies Affected: Indiana Health Professions Bureau, Board of Pharmacy, and the Department of Correction.

Local Agencies Affected: Trial courts, local law enforcement agencies.

Information Sources: Barbara McNutt, Chief Counsel, Health Professions Bureau, 317-234-1987; “Combating Counterfeit Drugs , A Report of the Food and Drug Administration, at: www.fda.gov/initiatives/counterfeit/report02_04 ; the National Association of Boards of PharmacyR at: www.nabp.net ; Indiana Sheriffs’ Association; and the Department of Correction.

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